Quantib BV
℅ Mrs. Floor van Leeuwen
Quality and Regulatory Manager
Westblaak 106
Rotterdam, Zuid-Holland 3012 KM
THE NETHERLANDS

June 15, 2020

Re: K200899
Trade/Device Name: Quantib AI Node
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 31, 2020
Received: April 3, 2020

Dear Mrs. van Leeuwen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200899

Device Name
Quantib AI Node

Indications for Use *(Describe)*
Quantib AI Node is a software platform that provides visualization and annotation tools and enables external post-processing extensions for medical images.

The software platform is designed to support in qualitative and quantitative measurement, analysis, and reporting of clinical data.

The software platform provides means for storing of data and transferring data from and into other systems such as PACS. The software platform provides an interface to integrate processing extensions and custom input/output modules.

Quantib AI Node functionality includes:

- Interface for multi-modality and multi-vendor input/output of data, such as DICOM data
- Initiation of extensions to process the data based on properties of the data
- Interface for extensions that provide custom data import/output, post-processing, and user interface functionality
- User interface for visualization and annotation of medical images, and for correction and confirmation of results generated by post-processing extensions

Quantib AI Node is intended to be used by trained medical professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Quantib AI Node 510(k) Summary

1 SUBMITTER

K200899

Quantib B.V.
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Phone: (+31) 108 41 17 49
Contact Person: Floor van Leeuwen, Quality & Regulatory Manager, Quality@Quantib.com
Date Prepared: March 31st, 2020

2 DEVICE INFORMATION

Name of Device: Quantib AI Node
Common or Usual Name: Quantib AI Node
Regulation Description: Picture archiving and communication system
Product Code: LLZ
Regulation number: 892.2050
Device Class: II

3 PREDICATE DEVICES

Primary
Device: AI-Rad Companion
Manufacturer: Siemens
510(k) Reg. No: K183272
This predicate has not been subject to a design-related recall.
Device Class: II
Product Code: LLZ

Secondary
Device: IntelliSpace Portal Platform
Manufacturer: Philips
510(k) Reg. No: K162025
This predicate has not been subject to a design-related recall.
Device Class: II
Product Code: LLZ

4 DEVICE DESCRIPTION

Quantib AI Node (QBX) is a stand-alone software platform that enables external post-processing extensions for medical images and provides visualization and annotation tools. It can automatically process data received via a DICOM connection and automatically export results to external DICOM nodes. It allows for configuring workflows that can contain user-interaction steps to review and correct automatic results.

5 INDICATIONS FOR USE

Indications for use Quantib AI Node

Quantib AI Node is a software platform that provides visualization and annotation tools and enables external post-processing extensions for medical images.

The software platform is designed to support in qualitative and quantitative measurement, analysis, and reporting of clinical data.

The software platform provides means for storing of data and transferring data from and into other systems such as PACS. The software platform provides an interface to integrate processing extensions and custom input/output modules.

Quantib AI Node functionality includes:

- Interface for multi-modality and multi-vendor input/output of data, such as DICOM data
- Initiation of extensions to process the data based on properties of the data
- Interface for extensions that provide custom data import/output, post-processing, and user interface functionality
- User interface for visualization and annotation of medical images, and for correction and confirmation of results generated by post-processing extensions

Quantib AI Node is intended to be used by trained medical professionals.

Indications for use primary predicate device

AI-Rad Companion (Engine) is a software platform that provides basic visualization and enables external post-processing extension for medical images used for diagnostic purposes. The software platform is designed to support technicians and trained physicians in qualitative and quantitative measurement and analysis of clinical data. The software platform provides means for storing of data and for transferring data into other systems such as PACS systems. The software platform provides an interface to integrate processing extensions.

AI-Rad Companion (Engine) functionality includes:

- Interface for multi-modality and multi-vendor Input / Output of DICOM Data
- Check of data validity using information for DICOM tags
- Interface for extensions that provide post-processing functionality
- Confirmation user interface for visualization of medical images processed by extensions
- Configuration user interface for configuration of the medical device and extensions

Indications for use secondary predicate device

Philips IntelliSpace Portal Platform is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network.
The system allows networking, selection, processing and filming of multimodality DICOM images.
This software is for use with off-the-shelf PC computer technology that meets defined minimum specifications.
Philips IntelliSpace Portal Platform is intended to be used by trained professionals, including but not limited to physicians and medical technicians.
This medical device is not to be used for mammography.
The device is not intended for diagnosis of lossy compressed images.

Indications for use comparison

Quantib AI Node includes functionality that can initiate extensions to process data based on its properties. AI-Rad Companion (Engine) includes similar functionality. In Quantib AI Node, processing is initiated by DICOM tag checks and future processing extensions can do final DICOM tag checks for data validity. This is equivalent to the check on validity using DICOM tags that AI-Rad Companion (Engine) does.

Quantib AI Node only supports input and output of DICOM data, but also provides an interface to extend import/output functionality to other data types. This functionality is subject to bench testing (verification and validation). As processing of the data is equal for all input/output data formats, this functionality does not raise any questions on the effectiveness and safety of the device compared to its predicates.

Quantib AI Node provides an interface to extend the system with user interaction steps that can be developed in the context of future applications built on top of Quantib AI Node. This is also available in AI Rad Companion (Engine).

Quantib AI Node by default contains functionality to not only confirm results (such as in AI-Rad Companion (Engine)), but also to correct these results with common editing tools and to make annotations, such as ruler measurements and comments. This functionality is equivalent to that of the secondary predicate device, IntelliSpace Portal Platform.

Quantib AI Node provides functionality to report created annotations which is also part of the predicate devices.

Based on this comparison between the indications for use of Quantib AI Node and its predicate devices, we conclude that the intended use of these devices is equivalent.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison	Quantib AI Node	Siemens AI-Rad Companion (Engine) Primary predicate device K183272	Philips IntelliSpace Portal Platform Secondary predicate device K162025	
Target users	Trained medical professionals	Trained medical professionals	Trained medical professionals	*Equivalent*
Anatomical site	Any	Any	Any	*Equivalent*
Where used	Hospital	Hospital	Hospital	*Equivalent*
Human factors	User can approve or reject results	User interface confirmation	User can approve or reject results	*Equivalent – 2nd predicate*
	User can create and update ROIs	Not supported	User can create, save and load ROIs	
	User can add and update annotations to analysis	Not supported	User can create image annotations	
Design	Platform with an interface for extensions that provide custom data import/output, post-processing, and user interface functionality	Platform with an interface for extensions that provide post-processing functionality	Platform that allows multiple users to remotely access clinical applications from compatible computers on a network.	*Equivalent*
Performance data				
Non-clinical Performance	Bench testing performed to test the functionality of the system and measurement tools.	Bench testing performed to test the functionality of the system.	Bench testing performed to test the functionality of the system.	*Equivalent*
Standards met	• IS0 14971 • IEC 62304 • IEC 62366	• IS0 14971 • IEC 62304 • IEC 62366	• IS0 14971 • IEC 62304	*Equivalent – 1st predicate*
SW verification and validation	Tested in accordance with verification and validation processes and planning. The testing results support that all the system requirements have met their acceptance criteria and are adequate for its intended use.	The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.	The system was tested in accordance with verification and validation processes The system meets the acceptance criteria and is adequate for its intended use.	*Equivalent*
Compatibility with environment and other devices	Conformance to NEMA PS 3.1-3.20 (2016) DICOM set. DICOM conformance statement included.	DICOM compatible	DICOM compatible	*Equivalent*
Reported measures				
Ruler tool	Available	Unknown	Unknown, but angle	*Partially*

			measurement tool available	*equivalent*
ROI Volume	Available	Available	Available	*Equivalent*
Required input	DICOM compatible data	DICOM compatible data	DICOM compatible data	*Equivalent*

For some of the technological characteristics compared above a more detailed description on their equivalency follows:

- *Human factor engineering:* The user workflow and user interaction functionalities of Quantib AI Node are partially equivalent to the primary predicate device and equivalent to the secondary predicate device. The user can confirm results in both Quantib AI Node and AI-Rad Companion (Engine). Annotation functionality, such as creating and updating ROIs and adding comments to the analysis, is equivalent to IntelliSpace Portal Platform.
- *Design:* The system design of Quantib AI Node is equivalent to both predicate devices. They all encompass a platform that can import (DICOM) data, perform automatic post-processing, provide the user with confirmation and annotation functionality, and export the resulting (DICOM) data.
- *Reported measures:* Quantib AI Node supports two types of standard measurements: a ruler/distance measurement tool and the ROI volume. The ROI volume measurement of Quantib AI Node is equal to the ROI measurement provided by both predicate devices. IntelliSpace Portal Platform contains an angle tool which is also a geometrical measurement tool in the same category of measurement functionality. The difference between the ruler/distance tool and the angle tool does not impact the safety and effectiveness of the device.

7 PERFORMANCE DATA

7.1 STANDARDS MET

Quantib AI Node was designed in compliance with the following US recognized consensus standards:

- ANSI AAMI ISO 14971:2007/(R)2010 – Medical devices - Application of risk management to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016 – Medical device software – Software life cycle processes
- ANSI AAMI IEC 62366-1:2015 – Medical devices- applications of usability engineering to medical devices

7.2 VERIFICATION AND VALIDATION ACTIVITIES

Quantib AI node has been tested in accordance with Quantib verification and validation processes and plan, addressing intended use, product claims, requirement specifications and risk management results. The testing results support that all the system requirements have met their pre-defined acceptance criteria.

The following quality assurance measures were applied to Quantib AI Node development:

- Risk and hazard analysis

- Design reviews
- Unit level testing
- Integration testing
- System testing
- Performance testing
- Usability engineering
- Cybersecurity analysis

7.3 NON-CLINICAL PERFORMANCE TESTING

Bench testing is done to show that the system is suitable for its intended use and that the measurement tool performance meets its pre-defined requirements. This did not reveal any issues with the system, demonstrating that the performance of Quantib AI Node is as safe and effective as its predicate devices.

7.4 SAFETY IMPLICATIONS

The differences between Quantib AI Node and the predicate devices do not affect the safety of the device compared to its predicates. This conclusion is based on:

- Failure mode and effects analysis on all functionality.
- Risk category classification of all software components.

Quantib AI Node and the predicate devices are all intended to support trained medical professionals in qualitative and quantitative measurement, analysis, and reporting of clinical data. The software does not make diagnoses; it provides a platform to support extensions that may present automatic measurements that must be interpreted by a trained medical professional before using them. Quantib AI Node and its predicates are all software applications running on off-the-shelve hardware; they do not have hardware components nor are they designed to provide a physical output to the user/patient. In conclusion, Quantib AI Node does not introduce any new safety issues compared to its predicates.

8 CONCLUSIONS

By virtue of its intended use, design features, and technological characteristics, Quantib AI Node is substantially equivalent to a device that has been approved for marketing in the United States. The non-clinical performance data in this 510(k) premarket notification shows that Quantib AI Node is as safe and effective as the predicate devices without raising any new safety and/or effectiveness concerns.